Reply to Office Action of: May 4, 2007

CLAIMS

The current claim set of the application is presented below. Indications as to the status of the claims appear in parentheses after the claim number. Deletions are identified in double brackets or strikethrough (e.g. [[deletion]] or deletion) and new text is identified with double underlining (e.g. new language).

1. (Currently amended) A method of delivering a denervating agent to a prostate gland comprising:

inserting an imaging apparatus into a rectum of a patient;

generating one or more images of a prostate gland via the imaging apparatus;

inserting a spring loaded needle encased in a shaft through a perineum of the patient;

positioning a distal end of the spring loaded needle in proximity to the prostate gland at a first location based on the one or more images;

actuating a spring mechanism to cause the distal end of the spring loaded needle to spring bias through a side of the shaft and into the prostate gland; and

delivering a dose of a denervating agent to the prostate gland at the first location via a lumen of the spring loaded needle.

- 2. (Previously presented) The method of claim 1, wherein generating one or more images of the prostate gland further comprises generating one or more images using an ultrasonic imaging device.
- 3. (Original) The method of claim 2, further comprising maneuvering the ultrasonic imaging device to generate the one or more images of the prostate gland.
- 4. (Previously presented) The method of claim 1, wherein delivering a dose of a denervating agent includes delivering a dose of botulinum toxin.
- 5. (Previously presented) The method of claim 1, further comprising:

removing the distal end of the needle from the prostate gland at the first location; positioning the distal end of the needle in proximity to a second location of the prostate gland based on the one or more images;

actuating the spring mechanism again to cause the distal end of needle to spring bias into the prostate gland at the second location; and

delivering a second dose of the denervating agent to the prostate gland via the lumen of the needle.

6. (Previously presented) The method of claim 5, further comprising:
removing the distal end of the needle from the prostate gland at the second location;
positioning the distal end of the needle in proximity to a third location of the prostate
gland based on the one or more images;

actuating the spring mechanism again to cause the distal end of needle to spring bias into the prostate gland at the third location; and

delivering a third dose of the denervating agent to the prostate gland via the lumen of the needle.

7. (Previously presented) The method of claim 6, further comprising: removing the distal end of the needle from the prostate gland at the third location; positioning the distal end of the needle in proximity to a fourth location of the prostate gland based on the one or more images;

actuating the spring mechanism again to cause the distal end of needle to spring bias into the prostate gland at the fourth location; and

delivering a fourth dose of the denervating agent to the prostate gland via the lumen of the needle.

8. (Original) The method of claim 7, wherein each of the doses comprise approximately 0.5 milliliter of botulinum toxin.

9. (Original) The method of claim 1, further comprising delivering the denervating agent from a denervating agent delivery assembly that includes a reservoir to hold the denervating agent and an actuator to cause the denervating agent to flow from the reservoir through the lumen, wherein a hub and a fluid line attaches the reservoir to the needle.

- 10. (Original) The method of claim 1, further comprising delivering the denervating agent from a denervating agent delivery assembly that includes a first reservoir that holds a substantial amount of the denervating agent, a second reservoir to hold a first discrete dose of the denervating agent and an actuator to cause the denervating agent to flow from the second reservoir through the lumen, wherein a hub attaches the second reservoir to the needle and the second reservoir refills with a second discrete dose of the denervating agent from the first reservoir following delivery of the first discrete dose.
- 11. (Currently amended) A system for delivering a denervating agent to a prostate gland comprising:

an imaging apparatus sized for insertion <u>through a shaft</u> into a rectum of a patient to generate one or more images of a prostate gland;

a spring loaded needle for insertion through <u>the shaft and into</u> a perineum of the patient in proximity to the prostate gland based on the one or more images, the needle defining a lumen; and

a spring mechanism to bias the needle through a side of the shaft and into the prostate gland upon actuation such that a denervating agent can be delivered to the prostate gland through the lumen.

- 12. (Original) The system of claim 11, further comprising an actuator to actuate the spring mechanism to bias the needle into the prostate gland.
- 13. (Original) The system of claim 11, further comprising a denervating agent delivery assembly coupled to the needle to deliver the denervating agent through the lumen.

14. (Original) The system of claim 13, wherein the denervating agent delivery assembly includes a reservoir to hold the denervating agent and an actuator to cause the denervating agent to flow from the reservoir through the lumen.

- 15. (Original) The system of claim 14, wherein the second actuator comprises a plunger.
- 16. (Original) The system of claim 14, wherein further comprising a hub and a fluid line for attachment of the needle to the reservoir.
- 17. (Original) The system of claim 13, wherein the denervating agent delivery assembly includes a first reservoir to hold a substantial amount of the denervating agent, a second reservoir to hold a discrete dose of the denervating agent, and an actuator to cause the denervating agent to flow from the second reservoir through the lumen, wherein the second reservoir refills with another discrete dose of the denervating agent from the first reservoir following actuation of the second actuator.
- 18. (Original) The system of claim 13, wherein the denervating agent delivery assembly includes a second actuator, a pump and a reservoir, wherein upon actuation of the second actuator the pump causes delivery of the denervating agent from the reservoir through the lumen.
- 19. (Original) The system of claim 11, wherein the denervating agent includes botulinum toxin.
- 20. (Original) The system of claim 11, wherein the imaging apparatus comprises an ultrasonic imaging apparatus.
- 21. (Original) The system of claim 11, wherein the needle includes a hyper-echoic coating.

22. (Previously presented) A system for delivering a denervating agent to a prostate gland comprising:

an imaging apparatus sized for insertion into a rectum of a patient to generate one or more images of a prostate gland, the imaging apparatus including a transurethral shaft;

a spring loaded needle for insertion through the transurethral shaft and through a perineum of the patient in proximity to the prostate gland based on the one or more images, the needle defining a lumen, wherein the spring loaded needle is operably attached to a wheel to permit rotation of the needle while in the shaft to a desired orientation relative to the prostrate gland; and

means for spring-biasing the needle into the prostate gland such that a denervating agent can be delivered to the prostate gland through the lumen.

- 23. (Original) The system of claim 22, further comprising means for delivering the denervating agent through the lumen.
- 24. (Currently amended) A method of delivering a denervating agent to a prostate gland comprising:

inserting an imaging apparatus into a rectum of a patient through a shaft; generating one or more images of a prostate gland via the imaging apparatus; inserting a spring loaded needle through a perineum of the patient, the spring loaded needle extending through a the shaft;

positioning a distal end of the spring loaded needle in proximity to the prostate gland based on the one or more images;

actuating a spring mechanism to cause the distal end of the needle to spring bias into the prostate gland through a side of the shaft at a first location;

delivering a first dose of the denervating agent to the prostate gland via the lumen of the needle;

repositioning the distal end of the needle in proximity to a second location of the prostate gland based on the one or more images, wherein repositioning the spring loaded needle includes rotating the needle in the shaft by actuation of a wheel;

actuating the spring mechanism again to cause the distal end of needle to spring bias into the prostate gland through a side of the shaft at the second location; and

delivering a second dose of the denervating agent to the prostate gland via the lumen of the needle.